Original Article

The efficacy of fluoride varnish vs a filled resin sealant for preventing white spot lesions during orthodontic treatment: *A randomized clinical trial*

Lauren N. Flynn[a]; Katie Julien[b]; Amal Noureldin[c]; Peter H. Buschang[d]

ABSTRACT

Objectives: To compare the efficacy of casein phosphopeptide (CPP)-amorphous calcium phosphate (ACP) MI Varnish (GC America, Inc, Alsip, IL) and ProSeal (Reliance Orthodontic Products, Itasca, IL) sealant in preventing the development of white spot lesions (WSLs) in orthodontic patients.

Materials and Methods: This prospective randomized clinical trial included 40 orthodontic patients 12–17 years of age. One group had sealants placed on their anterior maxillary teeth, with reapplications every 3 months. The other group had MI Varnish applied every 4–6 weeks. WSL formation and oral hygiene were evaluated at the initial appointment before bonding (T1) and 12 months later (T2). Standardized digital photographs were analyzed using the enamel decalcification index (EDI). Statistical comparisons were made using independent and paired-sample *t*-tests as well as chi-square tests.

Results: In this trial, 43% of patients and 15% of teeth developed new WSLs. Lateral incisors showed the highest incidence of decalcification and WSL formation. WSL formation and EDI score increases during treatment were significantly greater in the gingival region than in the mesial, distal, or incisal regions. Of the EDI scores at T2, 93.8% were 0 and 5.5% were 1. Poor oral hygiene at T2 showed a high positive predictive value (76%) for the development of WSLs. There were no statistically significant between-group differences for the development of WSLs.

Conclusions: MI Varnish and ProSeal sealant provided similar levels of protection during the first 12 months of fixed orthodontic treatment. The severity of the WSLs that developed was minimal. WSLs were most likely to develop on lateral incisors and in the gingival regions of teeth, especially among patients with poorer oral hygiene. (*Angle Orthod.* 2022;92:204–212.)

KEY WORDS: White spot lesions; EDI scores; CPP-ACP MI Varnish; ProSeal sealant; In vivo RCT

INTRODUCTION

White spot lesions (WSLs) represent the first sign of the caries process and are a common sequela of orthodontic treatment.[1] The most common location for developing these lesions is on the gingival portion of the labial surface of the teeth.[2,3] The teeth most commonly affected are the maxillary lateral incisors and canines.[4,5] Although minor WSLs can remineralize posttreatment when exposed to fluoride and minerals,[6] those that remain visible pose esthetic problems for patients and potential medicolegal concerns for orthodontists.

The most widely used method used to prevent demineralization is the application of fluoridated products and sealants onto the enamel surfaces.[7] Fluoride prevents enamel demineralization and can remineralize existing WSLs. Fluoride toothpaste and mouth rinse are problematic because each requires compliance. Fluoride varnish provides longer lasting protective effects than toothpaste or mouth rinse.[8] MI Varnish (GC America, Inc, Alsip, IL), which contains sodium fluoride (NaF) and casein phosphopeptide (CPP)-amorphous calcium phosphate (ACP), has been

[a] Private Practice, Flower Mound, Tex, USA.
[b] Clinical Associate Professor, Department of Orthodontics, Texas A&M University College of Dentistry, Dallas, Tex, USA.
[c] Associate Professor, Department of Public Health Sciences, Texas A&M University College of Dentistry, College of Dentistry, Dallas, Tex, USA.
[d] Regents Professor and Director of Orthodontic Research, Department of Orthodontics, Texas A&M University College of Dentistry, Dallas, Tex, USA.
Corresponding author: Dr Peter H. Buschang, Professor and Director of Orthodontic Research, Orthodontic Department, Texas A&M University College of Dentistry, Dallas, TX 75246 (e-mail: phbuschang@tamhsc.edu)

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shown in vitro to be superior to fluoride varnish with NaF alone in preventing incipient caries.[9] In vitro, MI Varnish prevented enamel demineralization for at least 4 weeks.[10] The only in vivo study of MI Varnish showed that reapplications every 3 months did not decrease WSLs any more than a fluoride toothpaste and rinse protocol.[11]

Sealants act as physical barriers to bacterial acid and plaque.[12] Although they are effective in preventing WSLs,[13,14] sealants come off over time, especially in the gingival region, leaving the enamel surface exposed to plaque and bacterial acid.[15] Sealants such as ProSeal (Reliance Orthodontic Products, Itasca, IL) have been shown to completely inhibit enamel demineralization as long as they remain on the teeth.[16] However, maintaining a protective coating of sealant on the teeth requires reapplication every few months.[15]

The purpose of the present study was to compare the clinical efficacy of MI Varnish and ProSeal sealant in preventing WSL formation in orthodontic patients. It is presently unknown if MI Varnish prevents the development of WSLs in orthodontic patients when applied every 4–6 weeks. In addition, it remains to be established if it is more effective to regularly reapply ProSeal as it wears away or to regularly reapply MI Varnish.

MATERIALS AND METHODS

This study was a single-center, parallel, randomized clinical trial performed between October 2018 and March 2020. The Texas A&M University Institutional Review Board (IRB) approval was obtained (IRB no. 2018-0724-CD-FB), and the study was registered with the US National Institutes of Health (ClinicalTrials.gov). No modifications to the study design were implemented during the study.

A total of 40 patients starting orthodontic treatment at Texas A&M University College of Dentistry orthodontic department were selected based on the following criteria: willingness to participate, no significant medical history, no underlying medical problems requiring more than two medications (to prevent bias of possible dry mouth), younger than 17 years of age at the start of orthodontic treatment, fully erupted and unrestored permanent maxillary canines and incisors, starting fixed orthodontic treatment, and ability to come to appointments every 4–6 weeks. Exclusion criteria included professional fluoride application in the past 3 months, allergy to milk, untreated cavitated lesions, heavy initial fluorosis, dry mouth, pregnancy, and any illness/condition that the investigators felt would affect the study outcome.

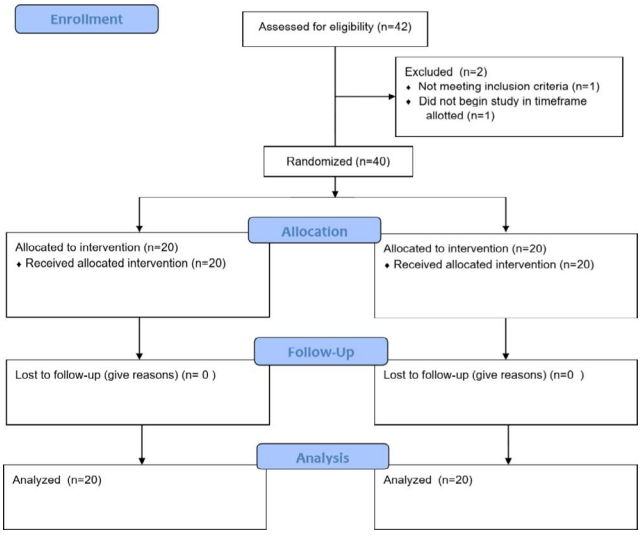

Figure 1. Study flow diagram.

Sample Size and Randomization

Sample sizes were determined based on estimates provided by a previous study that compared MI Varnish with MI Paste Plus (GC America, Inc, Alsip, IL).[11] Assuming a standard deviation of 3, an effect size of 1.2, and a two-tailed test with an alpha error of .05, 12 patients were needed in each group to provide 90% power. Due to the possibility of patient dropout and noncompliance with the study protocol, a total of 40 patients were selected. None of the patients were lost to follow-up (Figure 1).

Block randomization of the patients was performed with Excel (Microsoft, Redmond, Wash) by an investigator who had no clinical involvement in the trial. Patients were assigned to either Group 1, which had ProSeal applied to the facial surfaces of the maxillary anterior teeth and reapplied every 3 months, or Group 2, which had MI Varnish applied to the maxillary anterior teeth every 4–6 weeks.

Interventions

The duration of the study was 0.99 $\pm$ 0.09 years for both groups (Table 1). Standardized oral hygiene instructions (proper brushing techniques and diet counseling) were given to all patients at the start of the study. The patients in Group 1 had the facial surfaces of their maxillary anterior six teeth etched for 15 seconds with 37% phosphoric acid etch gel and rinsed thoroughly. A thin layer of LED ProSeal was applied with a microbrush and light cured for 3 seconds. Brackets were bonded to the teeth using a thin layer of TransBond XT (3M, Maplewood, MN) composite. The integrity of the sealant was checked every 3 months with a black light, with reapplications

Table 1. Group Characteristics

	Sealant Group	Varnish Group
No. of patients	20	20
Average age, y	14.0	14.1
Boys/girls	10/10	8/12
Duration of treatment, y	0.99 ± 0.089	0.99 ± 0.091

when necessary. All teeth required reapplication of sealant on at least one area of a tooth every 3 months.

For Group 2, the facial surfaces of the maxillary teeth were etched for 15 seconds with 37% phosphoric acid etch gel and rinsed thoroughly. A thin layer of Assure Plus (Reliance Orthodontic Products, Inc., Itasca, Ill) was applied, and brackets were bonded using a thin layer of TransBond XT Composite. At the end of the appointment, the maxillary anterior teeth were dried with a dry air syringe and MI Varnish was applied to the facial surfaces. Instructions were given to not brush for the next 6 hours and avoid hard, crunchy foods per the manufacturer's instructions. Group 2 had MI Varnish reapplied every 4–6 weeks at their regular appointments. At the final appointment, the brackets, composite, bonding agents, and sealants of both groups were removed and photos were taken.

Oral Hygiene Evaluation

Oral hygiene was evaluated based on the accumulation of plaque on the anterior maxillary teeth using the Turesky modification of the Quigley and Hein plaque index.[17] It was assessed before preparing the teeth for bonding (T1) and before the brackets were removed 12 months later (T2).

Photographs

After the patients brushed their teeth, a NOLA (Ortho Technology, West Columbia, SC) cheek retractor was placed, the teeth were dried with a dry air syringe, and photographs of the maxillary anterior teeth were then taken before initial bonding. They were taken by the principal investigator under standardized lighting conditions using a Canon T5i (Canon U.S.A. Inc, Melville, NY) camera with a macro lens (F stop = 29, focus set to 2). One photograph was taken of the upper right canine and lateral incisor, another of the central incisors, and another of the upper left lateral incisor and canine. If there was glare, another photo was taken at a slightly different angle. The same three photos were again taken immediately after the brackets, sealant, and bonding agent were removed at the end of the study.

Enamel Decalcification Index and Computer Analysis

The patient photographs were randomized, and one blinded investigator performed all of the assessments.

Table 2. EDI Score[a]

EDI Score	Description
0	No decalcification
1	Decalcification covering <50% of the area
2	Decalcification covering >50% of the area
3	Decalcification covering 100% of the area or severe decalcification with cavitation

[a] Source: Banks and Richmond.[2]

The T1 and T2 photos were enlarged to corresponding sizes and compared side-by-side on a computer in a darkened room. The differentiation between a developmental enamel lesion and a decalcified WSL followed previous recommendations.[18] The enamel decalcification index (EDI) score was also used to evaluate the maxillary teeth.[2] All four regions on the facial surface of each tooth were evaluated (Table 2). After a 2-week interval, the four regions on 60 teeth of 10 randomly chosen patients were reevaluated. Overall, the scores were concordant 97.4% of the time, with the canines and lateral incisors showing the lowest (96.1%) and highest (98.7%) concordance, respectively.

Statistical Methods

EDI scores were summed for all six teeth at T1 and T2. Independent-sample *t*-tests were used to evaluate differences between the two groups for oral hygiene scores and overall EDI sums. Paired *t*-tests were used to evaluate differences between teeth as well as differences between tooth regions. The chi-square test was used to determine differences in WSL prevalence, incidence, and differences in EDI scores between different teeth and regions.

RESULTS

Entire Sample

Approximately 43% of patients and 15% of teeth developed WSLs during the study (Table 3). The EDI scores increased significantly, from 36 (T1) to 74 (T2). There was no statistically significant difference between boys and girls in the incidence of WSL formation ($P = .822$). Based on the percentage of teeth (9.5%) and percentage of patients (32.5%), the lateral incisors showed a significantly higher incidence of WSL formation than the central incisors and

Table 3. Incidence (T1–T2) of WSLs for All Patients

	Incidence (T1–T2)	
	Patients	Teeth
Percentage	42.5	14.9
n/N	17/40	35/240

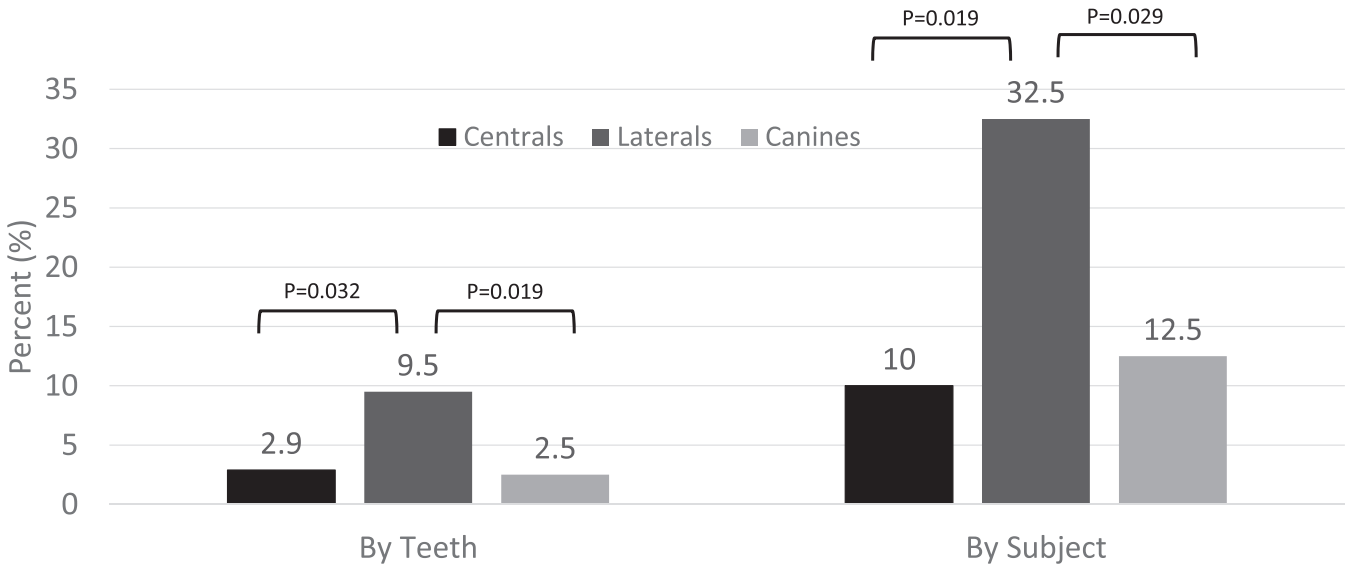

Figure 2. Incidence of WSL development based on tooth type.

canines (Figure 2). The lateral incisors also had the greatest increase of EDI scores over time (Figure 3). Based on the percentages of teeth (10.4%) and patients (32.5%), the incidence of WSL formation was significantly greater in the gingival than in the mesial, distal, or incisal regions (Figure 4). The gingival region also showed the greatest increase of EDI scores over time (Figure 5).

At T2, the EDI scores ranged from 0 to 3. Of all scores, 95.8% were 0. Of the scores indicating decalcification (ie, those ranging 1–3), 88.3% were scores of 1, 6.7% were scores of 2, and 5% were scores of 3. All of the 3 scores pertained to the same patient.

Although there were no differences at T1, the patients who had poor oral hygiene at T2 were more likely to develop WSLs than those who had good oral hygiene (Figure 6). Poor oral hygiene at T2 showed a high positive predictive value (76%) for the development of WSLs.

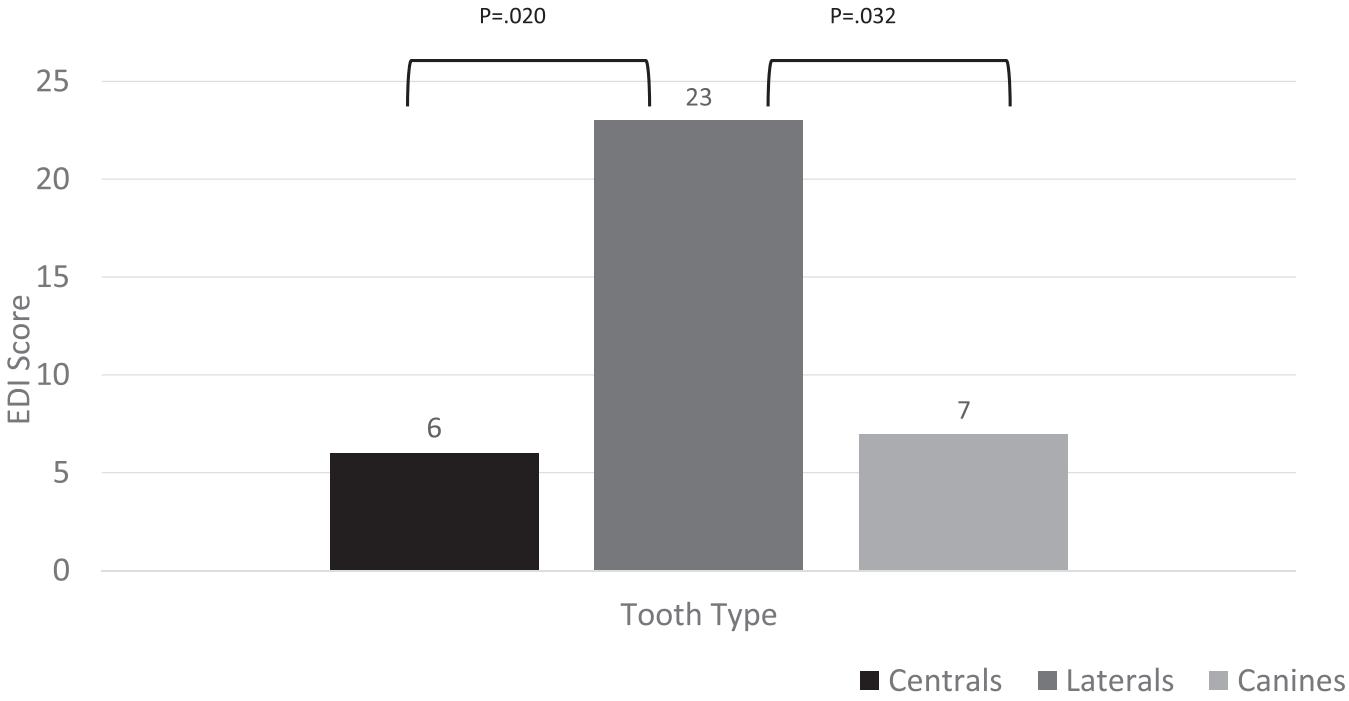

Figure 3. EDI changes by tooth type.

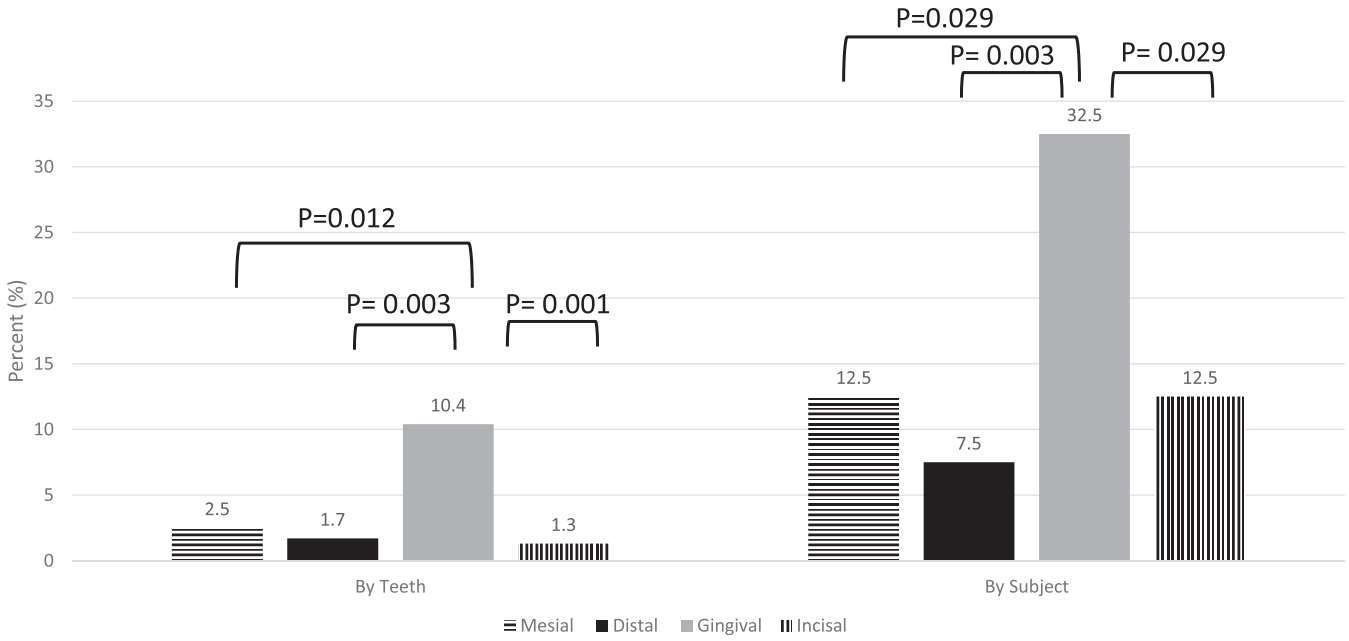

Figure 4. Percentage of patients who developed WSLs based on tooth region.

Group Comparisons

The incidence of both patients (50% vs 35%) and teeth (17.5% vs 12.5%) developing WSLs were greater in the sealant than in the varnish group, but the differences were not statistically significant (Table 4). Although there was no between-group difference at T1, oral hygiene scores were significantly higher in the sealant than in the varnish group at T2 (Figure 7). The between-group difference in the incidence of increasing EDI scores (ie, new decalcification not present at T1) was not statistically significant (Figure 8). Of the EDI scores greater than 0 (ie, indicating decalcification) at T2, 85% and 95% in the sealant and varnish group, respectively, were scores of 1 (Figure 9).

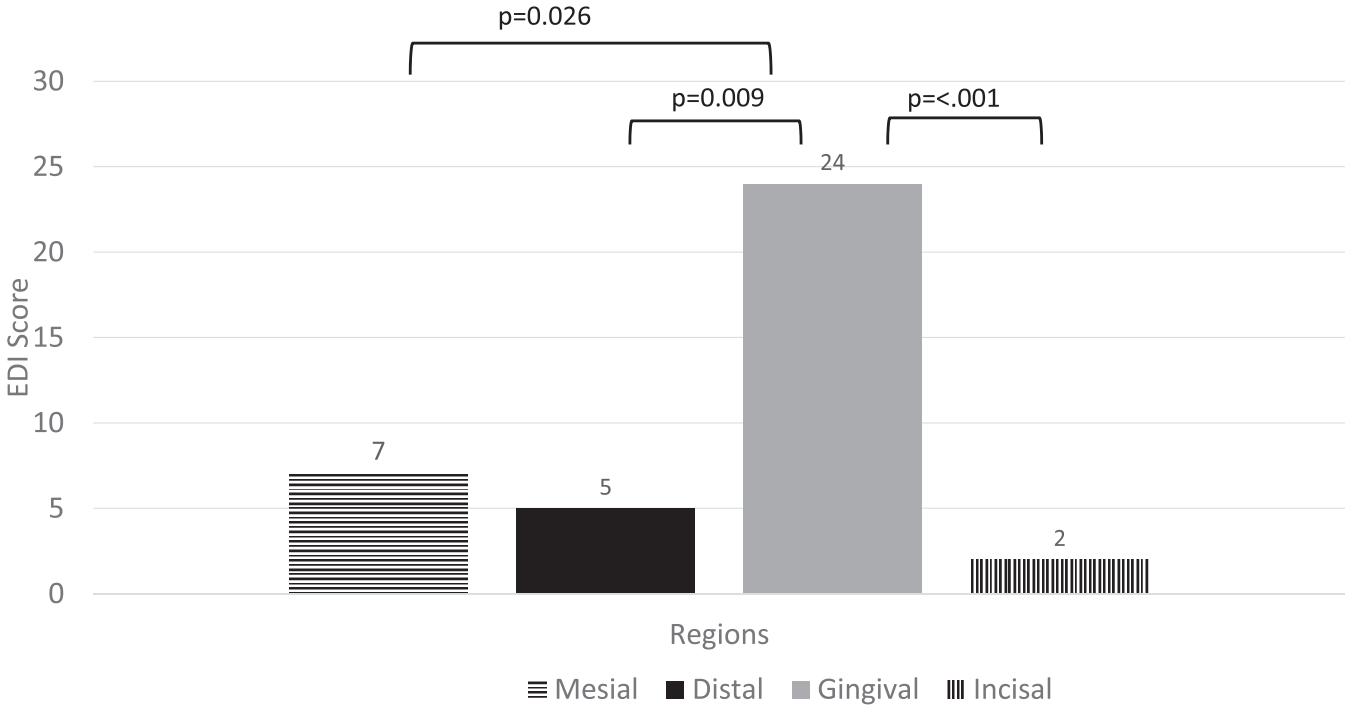

Figure 5. EDI changes by region.

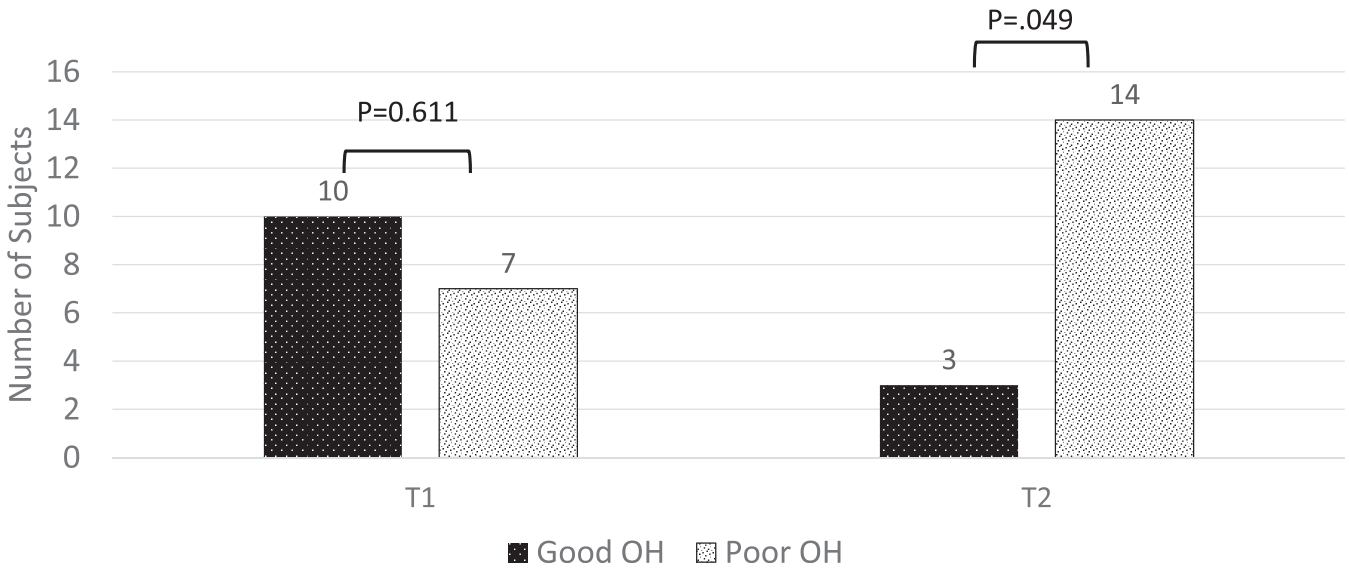

Figure 6. Overall number of patients who developed WSLs based on oral hygiene status at T1 and T2.

DISCUSSION

The incidence of teeth developing WSLs during orthodontic treatment can be low, even though the incidence of patients developing WSLs is relatively high. The literature reported that 16.7%–41.1% of teeth developed WSLs during orthodontic treatment.[11,19,20] In the present study, only 14.9% of the teeth developed WSL. The incidence of WSL formation among patients was 42.5% compared with 23%–36% in previous studies.[5,21] The higher incidence in the present study may have been attributed to (1) the higher pretreatment prevalence of WSLs, (2) the WSL detection methodology used, (3) T2 evaluations taking place immediately after debonding (before minor WSLs scored as 1 could remineralize), or (4) light reflection caused by desiccating and roughening the enamel after debonding.

Even though the incidence among patients was high, the severity of the WSLs that developed was minor. Of the EDI scores in the present study, 93.8% were 0 at the end of the study. Of the decalcification scores 1–3, 88.3% were scores of 1 (Figure 10), which could remineralize after exposure to fluoride and minerals in the saliva.[7] The only other in vivo study evaluating MI Varnish found that 46% of the EDI scores were 0 after 12 months.[11] Together, the substantially lower incidence of teeth developing WSLs and the lesser amounts of demineralization observed indicated a significant clinical reduction in decalcification with both of the treatments.

Table 4. Incidence of WSLs for Sealant and Varnish Groups

	Incidence Change	
	Patients	Teeth
Sealant		
Percentage	50	17.5
n/N	10/20	21/120
Varnish		
Percentage	35	12.5
n/N	7/20	15/120
Probability group differences	0.337	0.278

WSLs are more likely to develop in the gingival regions of teeth, especially the lateral incisors. The literature indicated that two-thirds of WSLs developed in the gingival region.[2,3] Plaque buildup around brackets is a precipitating factor for developing WSLs, and the plaque trap between the bracket and the gingiva makes the plaque challenge greater.[4] Lateral incisors have been previously shown to be the most common anterior tooth to develop white spots,[2–5,22] which might be expected because of the bracket's thicker profile and proximity to the gingiva.

MI Varnish and ProSeal provided similar levels of protection during orthodontic treatment. Both in vitro and in vivo studies have shown that sealants were effective.[13,14,23] ProSeal is a filled sealant that is more resistant to physical and mechanical wear than unfilled sealants[12] and can better withstand thermal, mechanical, and chemical loads than other sealants.[16] However, sealants should be reapplied every 3–4 months.[15] Even when reapplied every 3 months, ProSeal did not entirely prevent WSLs in the present study.

Fluoride varnish has positive preventive effects compared with no treatment,[8,9] and it is easier to regularly reapply than sealants, making it well suited for clinical applications in private orthodontic practices. Although the difference was not statistically significant,

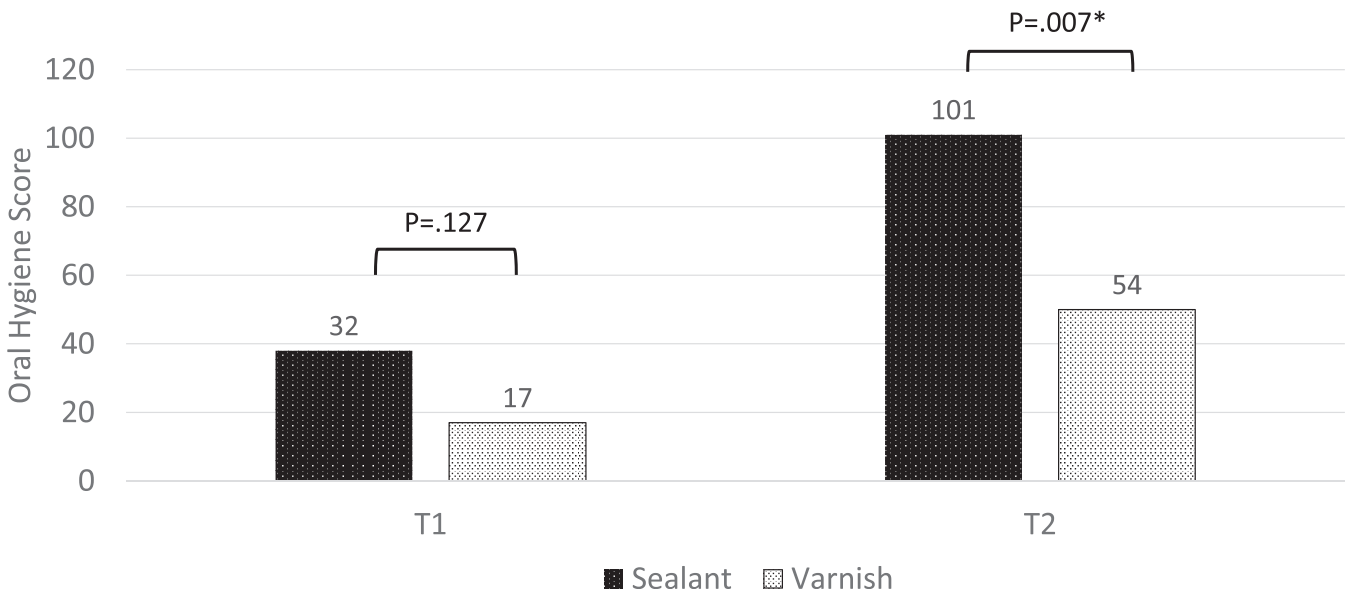

Figure 7. Group comparison of oral hygiene scores at T1 vs T2.

the sealant group had a higher incidence of WSLs and greater increases in EDI scores than the varnish group. With larger sample sizes, the differences would probably have been statistically significant. The only other in vivo study of MI Varnish showed that reapplications every 3 months did not decrease WSL development any more than the use of fluoride toothpaste and fluoride rinse.[11] They found that the EDI scores of 32.3% of teeth worsened over 12 months (compared with 12.5% in the present study when MI Varnish was applied at 4–6 week intervals). The 6-week reapplications of Fluor Protector (Ivoclarvivadent, Schaan, Liechtenstein), another fluoride varnish, was also shown to reduce the incidence of WSLs significantly more than no treatment.[24] Reapplying MI Varnish every 4-6 weeks appeared to increase its effectiveness and substantially limit demineralization, as previously demonstrated in vitro.[10]

At the end of the present study, patients who developed WSLs had poorer oral hygiene. Although there were no between-group differences at T1, hygiene was significantly better at T2 in the varnish group than in the sealant group, which could partially explain the higher EDI scores in the sealant group. Poor oral hygiene has previously been established as a significant risk factor for developing WSLs.[4,5,19]

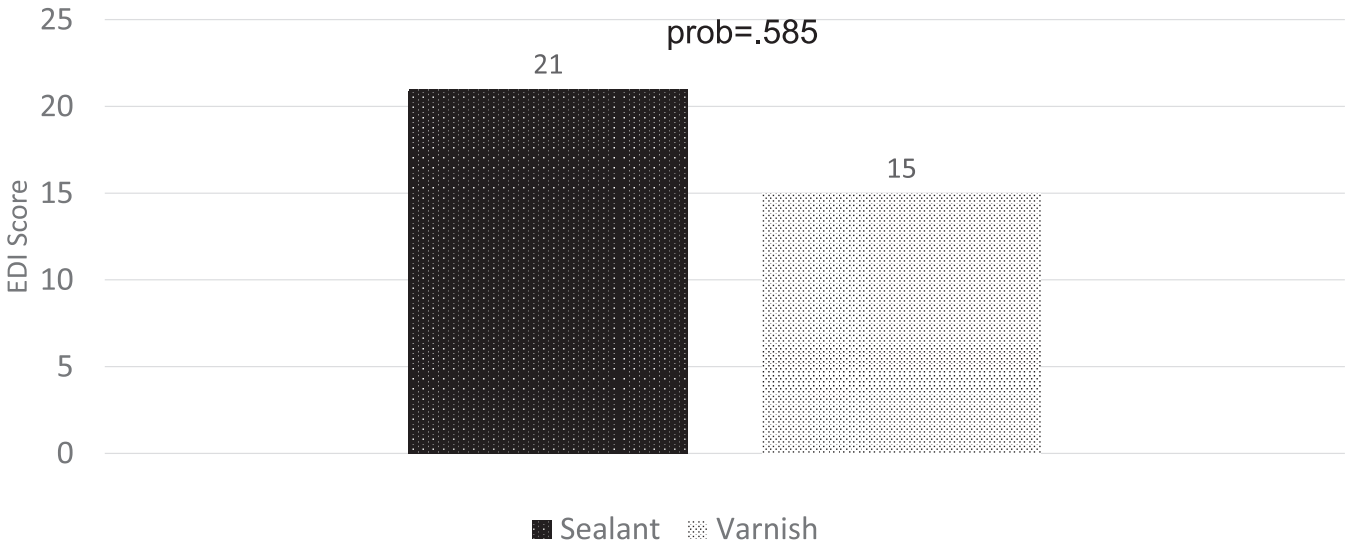

Figure 8. Total EDI scores developed during treatment for the sealant and varnish group.

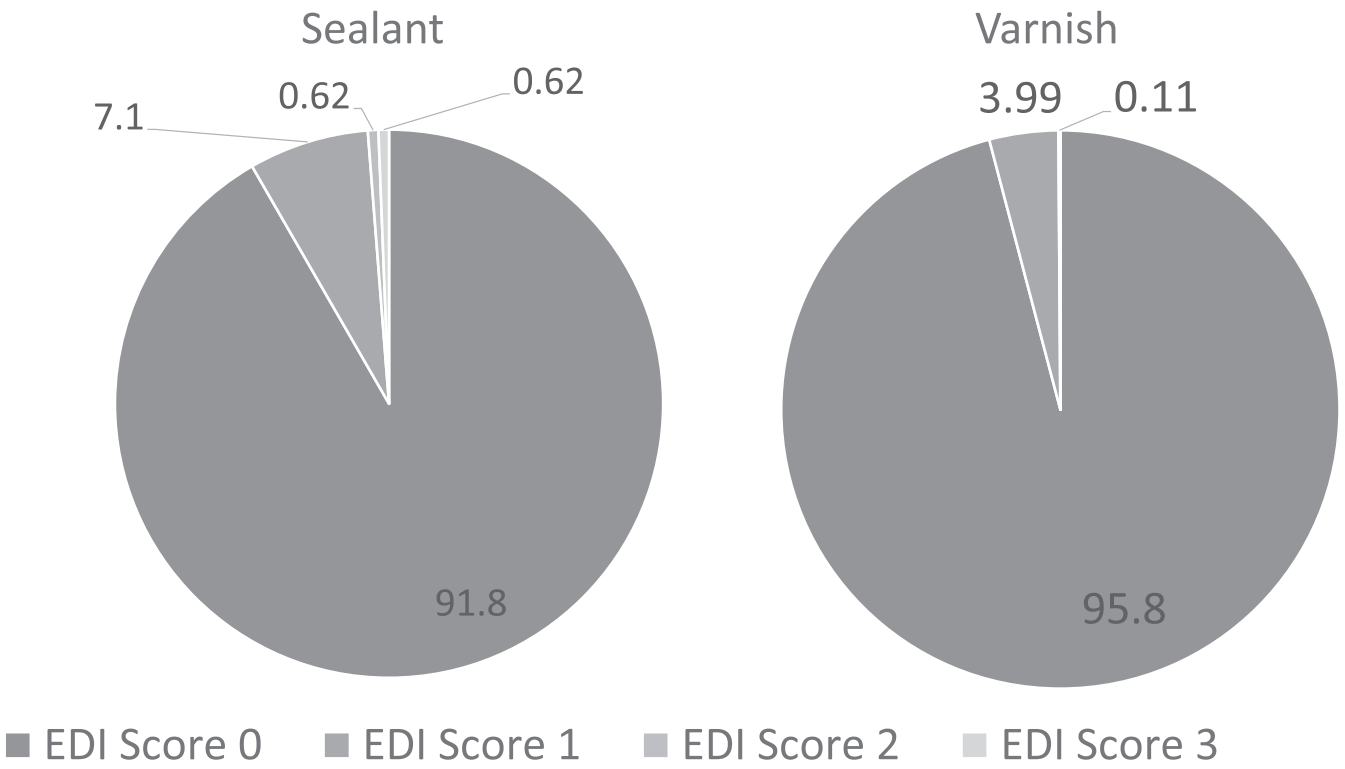

Figure 9. Percentage of regions with EDI scores of 0, 1, 2, or 3 at T2 for the sealant and varnish groups.

CONCLUSIONS

- When regularly reapplied, MI Varnish and ProSeal sealant provide similar levels of protection during orthodontic treatment, although varnish may be simpler to apply/reapply.
- Only 6.2% of all surfaces and 15% of all teeth showed decalcification during treatment.
- Although the incidence of WSLs among patients was high, the amount of decalcification that occurred was minimal.
- Lateral incisors are more likely to develop WSLs than canines and central incisors.
- The gingival region is more likely to develop WSLs than other regions of teeth.
- Patients who develop WSLs have poorer oral hygiene.

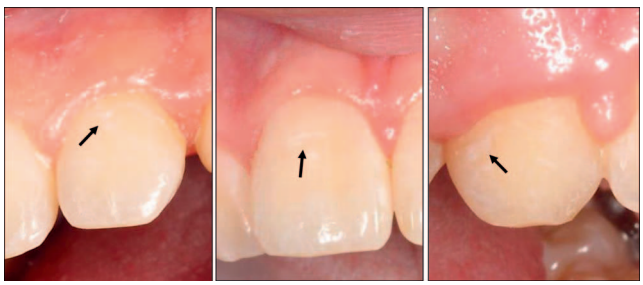

Figure 10. Variability between EDI scores of 1 indicating minimal decalcification, which might be expected to heal spontaneously after treatment.

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